K023690

510 (K) SUMMARY:

FEB 2 8 2003

The 510 (k) summary of Quick Disconnect Plug connector:

- Predicate Device:

  The Quick Disconnect Plug is substantially equivalent, but an improvement over the predicate preamendment device, which is a simple urinary catheter plug that stops the flow of urine from leaving the catheter.

- Device Description:

  The Quick Disconnect Plug is designed to facilitate a speedy, comfortable, and safe rehabilitation for patients requiring use of a urinary catheter. The use of a urinary catheter to facilitate drainage from the bladder is usual and customary following most surgery. In using a catheter, it is connected to a collection bag, which becomes a potential physical hazard and a source of discomfort to the patient in attempting to do rehabilitative exercise. The Quick Disconnect Plug allows the patient and/or attending nurse or physician to quickly disconnect the catheter from the drainage bag, leaving one half of the Quick Disconnect Device, which has a shut-off valve built in, in the open end of the catheter and seals off the flow of urine until such time as it is reconnected and the flow is once again resumed between the catheter and the collection bag.

- Technical Characteristics:

  The device is made up of two main components: (1) the body; and (2) the insert with the valve. Also included in the sterilized package is a vinyl tubing coupler.

  All components included above are made of non-toxic ingredients that meet USP Class VI requirements. Diagrams, drawings, and photographs of the above components are included and attached to this statement.

  One size is adequate to handle catheters up to and including size 26.

  Intended use of the device is for one-time use only for short durations of 2 weeks (14 days) or less with a 2-hour disconnection time interval from the bag before reconnection to evacuate the bladder. This is to be sold as a sterile product with a 5-year shelf-life. Corresponding paperwork to substantiate statement is enclosed.

  This device is sold with a restriction by order of a physician in accordance with 21 CFR 801.109.

510 (k) Summary (Continued):

- Performance Standards:

  None established.

- Sterilization

  Sterilization will be ETO (ethylene oxide) gas.

  Medsource Packaging Concepts is the company who will be packaging the product. Sterilization Services is the sterilization facility who will be processing the product.

  Medsource Packaging Concepts (FDA Registration #1125782) is a Manufacturer/ Repacker/Relabeler of finished devices which may be received nonsterile or sterile from the original manufacturer. Sterilization Services of Virginia (FDA Registration #1123137) is a contract sterilization facility located in Richmond, Virginia.

  The packaging method has been tested and proven to have a shelf-life of 5 years, and has been transportation tested over the past 15 years, and has shown no damage or deterioration caused by transportation of this product after sterilization.

- Labeling and Instruction Sheet.

  Labeling and instruction sheet to conform to device labeling guidance (Blue Book Memo G91-1). Picture of label and copy of instruction sheet to be included with this statement.

- Biocompatibility:

  Device is made of all USP Class VI material. Bioincompatibility and/or toxicity in using this device is virtually zero. Refer to biocompatibility statement enclosed.

- Safety and Effectiveness:

  This product is being manufactured and sterilized under government regulated guidelines and should cause no harmful effects to any patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

Mr. Martin Mitchell
World Metals Inc.
1020 NE 27th Avenue
Pompano Beach, FL 33062

Re: K023690
Trade/Device Name: Catheter Connector
Quick Disconnect Plug
Regulation Number: 21 CFR§ 876. 5130
Regulation Name: Urological catheter
and accessories
Regulatory Class: II
Product Code: 78 KNY
Dated: February 13, 2003
Received: February 14, 2003

Dear Mr. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

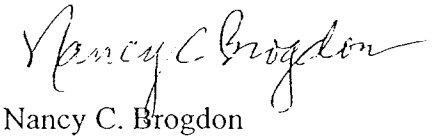
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023690

510 (k) Number: K023690

Device Name: Quick Disconnect Plug

Indications for Use:

The Quick Disconnect Plug is intended to stop the flow of urine from the urinary catheter to the drainage bag. It is intended for use on a short term basis of no longer than two weeks (14 days) duration. The daily disconnection schedule should not exceed two hours. This device is available sterile for one-time use by physician's prescription.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023690

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)